



## Complete Summary

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### **GUIDELINE TITLE**

Treatment delivery and community-based DR-TB support. In: Guidelines for the programmatic management of drug-resistant tuberculosis.

### **BIBLIOGRAPHIC SOURCE(S)**

Treatment delivery and community-based DR-TB support. In: World Health Organization (WHO). Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. 120-9. [17 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
QUALIFYING STATEMENTS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY

## SCOPE

### **DISEASE/CONDITION(S)**

Drug-resistant tuberculosis (DR-TB), including:

- Multidrug-resistant tuberculosis (MDR-TB)
- Extensively drug-resistant TB (XDR-TB)

### **GUIDELINE CATEGORY**

Counseling  
Management  
Prevention  
Treatment

## **CLINICAL SPECIALTY**

Infectious Diseases

## **INTENDED USERS**

Advanced Practice Nurses  
Allied Health Personnel  
Health Care Providers  
Health Plans  
Hospitals  
Managed Care Organizations  
Nurses  
Pharmacists  
Physician Assistants  
Physicians  
Public Health Departments  
Social Workers

## **GUIDELINE OBJECTIVE(S)**

- To outline the strategies for treatment delivery that will improve adherence among patients receiving treatment for drug-resistant tuberculosis (DR-TB)
- To disseminate consistent, up-to-date recommendations for the diagnosis and management of multidrug-resistant tuberculosis in a variety of geographical, political, economic and social settings
- To enable access to comprehensive, up-to-date, technical and clinical information on the prevention and management of DR-TB and to encourage the implementation of known best practice
- To assist in the development of national policies to improve the diagnosis and management of DR-TB

## **TARGET POPULATION**

Patients with drug-resistant tuberculosis (DR-TB)

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Management/Treatment**

1. Reliable network of educated providers (community, clinic, or hospital-based)
2. Adherence monitoring through the following:
  - Disease education
  - Directly observed therapy (DOT), maintaining confidentiality
  - Socioeconomic intervention
  - Psychosocial and emotional support (e.g., support groups, professional counseling, multidisciplinary support)
  - Management of adverse drug effects
3. Use of community care supporters

## **MAJOR OUTCOMES CONSIDERED**

- Rate of transmission
- Rate of nonadherence to therapy
- Side effects from therapy
- Morbidity and mortality

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases  
 Searches of Unpublished Data

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The nominated lead author for each chapter used a limited evidence retrieval consisting of:

- Personal collection of publications and case reports
- Literatures searches using PubMed and other databases and search engines
- Existing guidelines, both from World Health Organization (WHO) and from other internationally recognized organizations
- Expert consensus during several group meetings for specific topics
- Unpublished data, for example data supplied to the Green Light Committee by their approved multidrug-resistant tuberculosis (MDR-TB) management projects

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus  
 Subjective Review

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The evidence was synthesized by each lead author, but a formal quality assessment was not used. Given the relatively small field of experts in managing

drug-resistant tuberculosis, expert opinion was sought from several of the original researchers in the field. The evidence was not formally assessed or graded and there are no formal evidence summaries.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

A meeting of the World Health Organization (WHO) Guidelines Steering Group, together with several WHO advisers who had contributed to the 2006 edition, took place in April 2006. It was agreed that there was an urgent need for guidance on the best response to extensively drug-resistant tuberculosis (XDR-TB), based on the emerging evidence. The group identified the chapters to be reconsidered and the gaps to be addressed in this emergency update.

Of the total 18 chapters in the original guideline document, eight have been reviewed and substantially changed in response to the emerging evidence about multidrug-resistant tuberculosis and XDR-TB (chapters 1, 4, 5, 6, 7, 10, 12 and 18). One chapter is new (Chapter 19). The remaining chapters have undergone minor revisions to ensure consistency but have not been rewritten or had any new evidence included.

There was also a decision that a full review of the Guidelines will be started after the emergency update. The WHO Guidelines Review Committee was in place by January 2008 and had already developed draft Guidance for Emergency Guidelines which was used to guide best practice in the finalization of this emergency update.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

Cost is not explicitly considered as part of the recommendations, although the realities of human resources, socioeconomic issues and health system infrastructure are taken into consideration throughout the original guideline document.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The chapters were each reviewed by at least one, and usually several, members of the Guidelines Reference Group, from both within the World Health

Organization (WHO) Stop tuberculosis (TB) and human immunodeficiency virus (HIV) departments and outside external experts, as appropriate. One of the expert advisers on the Steering Group was commissioned to harmonize and review all the updated chapters. The remainder of the Steering Group also reviewed the whole document and provided extensive and detailed feedback.

The first draft of the guidelines was reviewed by the Steering Group at meeting held in February 2008. Other advisers at this meeting were Dr Malgosia Grzemska (WHO), Dr Suzanne Hill (WHO), Dr Tim Holtz (CDC, USA) and Dr Kathrin Thomas (WHO). Any outstanding issues were then resolved by e-mail to agree the final version. Other members of the group were asked to provide reviews at these later stages for particular issues.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### Key Changes for the Emergency Update 2008 Compared to the 2006 Guideline

- A section on community-based care and support is added to this chapter. National tuberculosis control programmes (NTPs) are encouraged to add community-based care and support into their national strategies and plans.

#### Key Recommendations (\*indicates updated recommendation)

- Use disease education, directly observed therapy (DOT), socioeconomic support, emotional support, management of adverse effects and monitoring systems to improve adherence to treatment.
- NTPs are encouraged to incorporate community-based care and support into their national plans.\*

#### Treatment Delivery Settings

Regardless of the mode of delivery, the management of drug-resistant tuberculosis (DR-TB) depends on a steady supply of medicines provided to patients free of charge through a reliable network of educated providers.

- **Community-based care.** Although early in the history of DR-TB treatment, strict hospitalization of patients was considered necessary, community-based care provided by trained lay and community health workers (CHWs) can achieve comparable results and, in theory, may result in decreased nosocomial spread of the disease. In each setting, care should be delivered by a multidisciplinary team of providers, including physicians, nurses, social workers and CHWs. The roles and responsibilities of each of these groups of providers will vary depending on the needs and resources available in specific settings. A more detailed description of community-based care and support is given in the section below.
- **Clinic-based treatment.** Some DR-TB treatment strategies involve the patient travelling to a clinic each day to receive DOT. This system works provided there is no barrier to travel or if the patient lives near a facility

offering DOT of DR-TB; the patient should be given an enabler for travel in situations other than these. The patient should be smear-negative if travelling on public transportation or waiting in common waiting rooms. Some facilities have a separate area with infection control measures for smear-positive patients. Special early morning appointments can be made for patients who need to get to work. An alternative version of this strategy is to have the clinic act as a "day hospital" where patients can rest or get a meal as an incentive for coming each day. Special attention must be taken in clinic-based programmes so that HIV-infected patients are not exposed to smear-positive patients.

- **Hospitalization.** Hospitals should provide acceptable living conditions, sufficient activities so that patients avoid boredom, adequate food, a heating system in cool areas, fans or cooling systems in hot climates and proper infection control measures. Infection control requirements are described in the National Guideline Clearinghouse (NGC) of the World Health Organization (WHO) guideline, [Drug resistance and infection control](#). Prisons require specific measures to improve adherence, which are described in detail in the WHO guidelines for [TB control in prisons](#).

## **Adherence to Therapy**

### *Disease Education*

Patients and their families should receive education about DR-TB, its treatment, potential adverse drug effects and the need for adherence to therapy. Educational interventions should begin at the start of therapy and continue throughout the course of treatment. Education can be provided by physicians, nurses, lay and CHWs and other health-care providers. Materials should be appropriate to the literacy levels of the population and should be culturally sensitive as well.

### *Directly Observed Therapy (DOT)*

Because DR-TB treatment is the last therapeutic option for many patients, and because there is a serious public health consequence if therapy fails in a patient with DR-TB, it is recommended that all patients receiving treatment for DR-TB receive DOT either in the community, at health centres or posts, or within the hospital setting. DOT should be provided in a way that does not place undue burdens on patients and their families. Long transportation times and distances, short clinic operation hours and difficulty in accessing services may all reduce the efficacy of DOT.

- **Who can deliver DOT?** When human and financial resources permit, the first choice for DOT delivery is to use health-care workers. Otherwise, trained community members can serve as effective DOT workers. With appropriate training and support, they can visit patients in their homes or workplaces. Receiving DOT from a community member is often a convenient alternative to the health centre and can result in excellent treatment adherence. However, community members need more intensive training, ongoing supervision by health professionals and support to deliver DOT for DR-TB than those who deliver DOT for drug-susceptible TB. It is recommended that the patient's DOT worker should not be a family member. Family relationships are often

- complicated for the DR-TB patient, and a family observer could be subject to subtle manipulation by the patient, relatives, employers, etc.
- **Maintaining confidentiality.** The DOT worker should explore the need to maintain strict confidentiality regarding the patient's disease. In some cases, this may entail working out a system whereby the patient can receive medication without the knowledge of others.

### *Socioeconomic Interventions*

Socioeconomic problems, including hunger, homelessness and unemployment, should be addressed to enable patients and their families to adhere to treatment. These problems have been successfully tackled through the provision of "incentives" and "enablers". Enablers are goods or services that make it easier for patients to adhere to treatment, such as the provision of transportation vouchers. Incentives are goods or services that are used to encourage patients to adhere to therapy, such as the provision of clothing. Maximal interventions should be given to patients with the most need. Programmes should benefit from professional social workers who can assess the need for such socioeconomic interventions and monitor their delivery. Socioeconomic interventions have included:

- Health care free of charge
- Food parcels for DR-TB patients and their dependents
- Temporary shelter in a housing facility or in a rented home for DR-TB patients
- School fees for dependent children
- Transportation fees
- Advice and assistance in administrative matters relating to the treatment
- Assistance in defending rights and/or reinforcing the responsibilities of patients
- Providing skills training and livelihood to patients both while on treatment as well as to prepare them with skills that can support them as they reintegrate into the community upon treatment completion

### *Psychosocial and Emotional Support*

Having DR-TB can be an emotionally devastating experience for patients and their families. Considerable stigma is attached to the disease and this may interfere with adherence to therapy. In addition, the long nature of DR-TB therapy combined with the adverse effects of the drugs may contribute to depression, anxiety and further difficulty with treatment adherence. The provision of emotional support to patients may increase the likelihood of adherence to therapy. This support may be organized in the form of support groups or one-to-one counselling by trained providers. Informal support can also be provided by physicians, nurses, DOT workers and family members. Most programmes use a multidisciplinary "support to adherence" team (social worker, nurse, health educator, companion and doctor).

### *Early and Effective Management of Adverse Drug Effects*

Although rarely life-threatening, the adverse effects of second-line drugs can be debilitating for patients. Patients experiencing high rates of adverse effects may be at increased risk of non-adherence. Therefore, early and effective management of adverse effects should be part of adherence-promotion strategies in the

management of DR-TB. In most cases, management of adverse effects can be accomplished using relatively simple and low-cost interventions without compromising the integrity of the DR-TB treatment regimen. Management of adverse effects is addressed in more detail in the NGC summary of the WHO guideline, [Initial evaluation, monitoring of treatment and management of adverse effects](#).

### *Monitoring and Follow-up of the Non-adherent Patient*

A strong system of monitoring that allows the patient to be followed throughout treatment must be in place. The forms in the National Guideline Clearinghouse (NGC) summary of WHO guideline, [Category IV recording and reporting system](#), are designed to assist the care provider in follow-up. When a patient fails to attend a DOT appointment, a system should be in place that allows prompt patient follow-up. Most often, this involves a DOT worker visiting the patient's home the same day to find out why the patient has missed an appointment and to ensure that treatment is resumed promptly and effectively. The situation should be addressed in a sympathetic, friendly and non-judgemental manner. Every effort should be made to listen to reasons for the patient missing a dose(s) and to work with patient and family to ensure continuation of treatment. Transportation problems should be addressed.

### **Community-Based Care and Support**

Community-based care and support is any action or help provided *by, with or from* the community, including situations in which patients are receiving ambulatory treatment. This support contributes to, and may even be necessary to, patient recovery. Political will from the health and local community authorities is vital to these efforts, and in settings with no tradition of community participation, it may help to involve organizations that have expertise in social mobilization and community organizing.

- **Community care supporters.** There are numerous potential supporters who can be brought into the effort to address programmatic needs on a local level. These include local health centre nurses, paid (and in some cases volunteer) CHWs, former and current patients, affected families, associations, cooperatives, grassroots organizations, local non-governmental organizations (NGOs), community volunteers and many more.
- **Function of the community care supporters.** Community care supporters can provide assistance in clinical management, DOT, contact tracing, infection control, recording and reporting, training, advocacy and social support.
  - *Clinical management.* This can come in the form of: (i) early detection of potentially serious adverse reactions and prompt referral of such reactions to health workers; (ii) provision of simple, non-medical measures to manage adverse reactions (e.g., oral hydration in mild diarrhoea, or counselling on the avoidance of alcohol while taking drugs that have hepatic effects, etc.) and (iii) psychological encouragement. This can often be most effective when coming from patients and former patients who endured the same adverse effects while on treatment.
  - *DOT.* Community-based support in DOT can be highly effective, especially if provided by former patients acting as treatment partners



for daily DOT, who are living proof that adherence to daily DOT pays and that there is hope for cure if they persevere with their treatment. Former patients also show better understanding, having gone through the same treatment themselves. Even when DOT is not provided by a former patient but by a local community member, it is a powerful act of solidarity. This solidarity is vital to new patients, who often feel isolated and vulnerable.

- *Contact tracing.* New cases can be discovered by community-care supporters through contact tracing. Early diagnosis of new cases may improve cure rates and acts as an important infection control measure.
- *Infection control.* Community-based support in infection control includes providing health education to patients on simple infection control practices that can be done in the home, such as observing cough etiquette (covering the mouth and nose when coughing, or sneezing), keeping one's room well ventilated by opening windows or staying outdoors as much as possible while visiting others.
- *Recording and reporting.* Data obtained within the family and community can contribute to better comprehensive management. This can include documenting processes occurring outside the health centre and closer to the patient's home. Recording certain variables during a home visit can better assess risks for the patient and family (such as leaky roofs, insufficient living space or poor sanitary conditions). Community-based support in recording and reporting may require close supervision and validation by health facility staff, and should be done in a manner that underlines "partnership".
- *Training/education.* Community-based training and education can come in the form of peer educators (i.e., former patients) or trained advocates. Topics can include general information on TB, how DR-TB develops, the treatment of DR-TB and the importance of adherence and infection control. Training and education on DR-TB will be most effective with the aid of materials written in lay language. WHO has issued guidelines for the development of teaching materials under strategies referred to as advocacy, communication and social mobilization (ACSM). These materials will be more effective if they contain input from patients. Patients can become part of a team that designs the text and visuals of materials for DR-TB patients. Topics such as the rights and responsibilities of patients as stated in the *Patients' charter for tuberculosis care* (available at [http://www.who.int/tb/publications/2006/istc\\_report.pdf](http://www.who.int/tb/publications/2006/istc_report.pdf)) should also be included. When former patients and care supporters participate in this health education process, it is more credible locally and serves also to raise awareness of TB in the wider community, strengthening basic TB control and care.
- *Advocacy and decreasing stigma.* Community-based supporters, often in the form of patients, give a voice and face to TB. The establishment of patient peer groups (community care club) and perhaps eventually a local organization or association can help reduce stigma and dispel inaccurate information about the disease. The groups can often influence decision-makers for policy change either in the clinics that they attend or in the wider community where they live.
- *Social support.* Community care supporters help identify socioeconomic and psychosocial needs and help channel support in a timely and more effective manner. They also help develop community

resources that may provide useful support, and encourage patients to contribute to the community by upholding their responsibilities (see also Socioeconomic Interventions and Psychosocial and Emotional Support above on socioeconomic and psychosocial interventions).

- **The relationship of community-based support and hospitalization for DR-TB.** CHWs and community-based support can facilitate timely access to the hospital, as hospitals and emergency services sometime reject DR-TB patients, making advocacy necessary. During hospitalization, the community-based network can continue to accompany patients and provide additional support as needed. With an efficient network for community-based care, the patient will be able to return to ambulatory treatment sooner, resulting in less nosocomial transmission, reduced hospitalization costs and more hospital beds available for other patients. Understanding and compassion are often lacking in hospitals that cater to general diseases because of health workers' fear of contracting DR-TB, as well as lack of experience in dealing with DR-TB.
- **Costs and sustainability.** When care is rooted in the community, ownership by the community supporters will make the support more sustainable. The CHW is often the backbone of a community-based support network. These guidelines advocate for trained CHWs who are a certified part of the health system and who receive a regular stipend that is a reasonable compensation for the amount of time that they spend each day participating in community-based care. The added cost of a strong CHW network is often cost effective because it contributes to lower rates of failure and prevention of further drug resistance.
- **Monitoring the CHW.** As stated, the CHW is often the backbone of the community-based network. Monitoring of the CHW can involve supervisors who perform unannounced or ad hoc visits to the patient. At these visits, they can perform pill counts, examinations of the treatment card and assess how activities are being carried out. Whenever a patient is doing poorly, a home visit and assessment of DOT should be performed. It is important to monitor the health status of CHWs and teach them how to protect themselves against TB transmission as well to ensure that they themselves do not develop disease. Weekly/monthly reports from the CHWs or those providing care in the community should be required. A communication network should be clear and in place, making sure that community volunteers have easy access to professional health staff should there be problems that arise in the community (e.g., adverse events or questions asked by patients that the CHWs cannot answer).

## Conclusion

Treatment delivery to patients with DR-TB can be accomplished in even the most resource-poor settings. It may be carried out using a hospital-, clinic or community-based approach, depending on the programme's organization and resources. Trained community members who are closely supervised on an ongoing basis can play an important role in the management of DR-TB in the NTP. Therefore, NTPs should be encouraged to incorporate community-based care and support into their national plans. Non-adherence to treatment is one of the primary factors leading to poor outcomes for patients with DR-TB. There are many reasons why patients may not adhere to therapy, and many of these stem from socioeconomic constraints. Higher rates of adherence can be achieved if patients are offered a comprehensive package of services, including disease education,

DOT, socioeconomic support, emotional support, management of adverse effects and monitoring systems to improve adherence. The human resources required to deliver the proper support should not be underestimated (see Chapter 16, "Human resources: training and staffing" in the original guideline document). Provision of the services and strategies discussed in this chapter should be viewed as an essential part of DR-TB treatment programmes worldwide, not only as a method of improving clinical and epidemiological outcomes but also in solidarity with each member of the community, especially those in greatest need. The political will needed to ensure integration of community initiatives with local and national TB programme activities demonstrates a commitment to the right to health and promotes participation in activities promoting the common good. Empowering the community and the individual recognizes and reinforces the dignity of each person.

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is not specifically stated for each recommendation.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate treatment and community-based support for patients with drug-resistant tuberculosis (DR-TB)

### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

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## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms  
Foreign Language Translations

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better  
Living with Illness  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Treatment delivery and community-based DR-TB support. In: World Health Organization (WHO). Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. 120-9. [17 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

**DATE RELEASED**

2008

**GUIDELINE DEVELOPER(S)**

World Health Organization - International Agency

**SOURCE(S) OF FUNDING**

UK Department for International Development  
United States Agency for International Development

**GUIDELINE COMMITTEE**

Not stated

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE****Steering Group**

*Chief Editor:* Michael Rich

*Editors-in-chief:* Ernesto Jaramillo; Salmaan Keshavjee; Kitty Lambregts; Karen Weyer

**Guidelines Reference Group**

Jaime Bayona, Socios En Salud, Sucursal Peru, Lima, Peru; Jose Caminero, International Union Against Tuberculosis and Lung Disease, Paris, France; Richard Coker, London School of Hygiene and Tropical Medicine, London, UK; Charles Daley, National Jewish Medical and Research Center, Denver, CO, USA; Hamish Fraser, Partners In Health, USA; Jennifer Furin, Partners In Health, Boston, MA, USA; Giuliano Gargioni, WHO Stop TB Department, Geneva, Switzerland; Haileyesus Getahun, WHO Stop TB Department, Geneva, Switzerland; Charles Gilks, WHO HIV Department, Geneva, Switzerland; Case Gordon, World Care Council, Geneva, Switzerland; Reuben Granich, WHO HIV Department, Geneva, Switzerland; Diane Havlir, University of California, San Francisco, CA, USA; Einar Heldal, Independent consultant; Tim Holtz, United States Centers for Disease Control and Prevention, Atlanta, GA, USA; Phil Hopewell, University of California, San Francisco, CA, USA; Ernesto Jaramillo, WHO Stop TB Department, Geneva, Switzerland; Salmaan Keshavjee, Partners In Health, Harvard Medical School, Boston, MA, USA; Catharina (Kitty) Lambregts van Weezenbeek, KNCV Tuberculosis Foundation, Netherlands; Vaira Leimane, State Agency of Tuberculosis and Lung Diseases, Latvia; Refiloe Matji, University Research Corporation, South Africa; Fuad Mirzayev, WHO Stop TB Department, Geneva, Switzerland; Carole Mitnick, Harvard Medical School, Boston, MA, USA; Christo van Niekerk, Global Alliance for TB Drug Development; Domingo Palmero, Hospital Muniz, Buenos Aires, Argentina; Geneviève Pinet, WHO Legal Department, Geneva, Switzerland; Mamel Quelapio, Tropical Disease Foundation, Philippines; Michael Rich, Partners In Health/Division of Social Medicine and

Health Inequalities, Brigham and Womens Hospital, Boston, MA, USA; Vija Riekstina, State Agency of Tuberculosis and Lung Diseases, Latvia; Irina Sahakyan, WHO Stop TB Department, Geneva, Switzerland; Fabio Scano, WHO Stop TB Department, Geneva, Switzerland; Adrienne Socci, Partners In Health, Boston, MA, USA; Kathrin Thomas, WHO Stop TB Department, Geneva, Switzerland; Arnaud Trébucq, International Union Against Tuberculosis and Lung Disease, Paris, France; Francis Varaine, Médecins Sans Frontières, France; Marco Vitoria, WHO HIV Department, Geneva, Switzerland; Fraser Wares, WHO Regional Office for South-East Asia, New Delhi; Karin Weyer, WHO Stop TB Department, Geneva, Switzerland; Abigail Wright, WHO Stop TB Department, Geneva, Switzerland; Matteo Zignol, WHO Stop TB Department, Geneva, Switzerland

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

All of the above contributors completed a WHO Declaration of Interest form.

The following interests were declared:

Case Gordon declared that he is an unpaid advocate for patients with anti-TB drug resistance and for improved access to high-quality care. He declared that he has himself survived XDR-TB.

Tim Holtz declared that he is an unpaid technical adviser and member of the Scientific Advisory Board of a manufacturer of anti-TB products, to advise on the development of a new anti-TB compound that will be tested in clinical trials of MDR-TB regimens.

Salmaan Keshavjee declared that his employer received funding from a foundation associated with a manufacturer of anti-TB products to support the research and training unit that he is heading.

Carole Mitnick declared that she is serving as a paid member of the Scientific Advisory Board of a manufacturer of anti-TB products, to advise on the development of a new anti-TB compound that will be tested in clinical trials of MDR-TB regimens.

Michael Rich declared that his employer received funding from a manufacturer of anti-TB products, in support of his salary.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in English, Chinese, and French in Portable Document Format (PDF) from the [World Health Organization Web site](http://www.who.int).

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: [bookorders@who.int](mailto:bookorders@who.int).

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Executive summary. Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. xi-xvi. Electronic copies: Available in Portable Document Format (PDF) from the [World Health Organization Web site](#).

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: [bookorders@who.int](mailto:bookorders@who.int).

In addition, various forms, registers, and reports are available in the appendices of the [original guideline document](#).

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI Institute on September 3, 2009. The information was verified by the guideline developer on December 11, 2009.

## COPYRIGHT STATEMENT

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